

II. REMARKS

Claims 2, 6-12, 15-17 and 39-41 were pending in the application. Applicant has amended claims 2, 15 & 39 and canceled claim 41. Thus, claims 2, 6-12, 15-17 and 39-40 are now pending in the application.

In a Notice of Allowance dated April 14, 2003, the Examiner allowed claims 2, 6-12, 15-17 and 39-41. In response, Applicant filed an RCE to submit an Information Disclosure Statement for the Examiner's consideration. The Examiner then issued an office action dated August 7, 2003 in which he rejected claims 39-41 but stated that claims 2, 6-12, and 15-17 are allowed. The Applicant filed a response dated November 7, 2003 traversing rejection of claims 39-41 and thanking the Examiner for allowing claims 2, 6-12, and 15-17. In the present office action, the Examiner has not only rejected claims 39-41 but has now also rejected previously allowed claims 2, 6-12, and 15-17. Such an action is highly unusual. See MPEP § 706.04

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

The Examiner rejected claims 2, 6-12, 15-17, and 39-41 under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (USPN 5,824,037). Applicant respectfully disagrees.

Applicant respectfully submits that Fogarty does not anticipate under § 102 because it does not disclose every limitation of the claimed invention. For a prior art reference to anticipate under 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. These elements must be arranged as in the claims under review. In re Bond, 910 F.2d 831, 832 (Fed. Cir. 1990).

As an initial matter, the Examiner has not presented any evidence to establish that every limitation of the rejected claims is shown in Fogarty. Thus, for example, the Examiner has not established that Fogarty shows a lever arm for precisely driving the sleeve. Likewise, the Examiner presents no evidence that Fogarty shows means for delivering contrast media, etc.

In any event, Applicant has amended the claims to further distinguish the claimed invention over Fogarty. Applicant has amended independent claims 2, 15 and 39 to specify the sleeve as "flexible." Applicant has also amended independent claim 39 to further limit the prosthesis as being a self-expanding stent. Support for the amendments is found, for example, on page 6, ll. 9-19, which describe the sleeve as being flexible; and page 3, ll. 1-10 for a self-expanding stent as a prosthesis.

United States Patent No. 5,824,037 to Fogarty describes a delivery system that includes an outer shaft enclosed within a cover. However, the cover disclosed in Fogarty is distinguishable from the sleeve of the present invention in several respects. First, the cover disclosed in Fogarty is not described as a flexible sleeve. In fact, Fogarty does not even characterize the cover as being flexible. As would be obvious to one of skill in the art, a self-expanding stent must be housed in a flexible housing and, therefore, the cover disclosed in Fogarty would not work with a self-expanding stent.

Further, the cover of Fogarty is integral with the delivery system shown in Figure 2 and extends over the entire length of the outer shaft. Thus, Fogarty provides:

Referring now to FIG. 2, an exemplary delivery catheter 30 for use with the endoluminal prostheses of the present invention comprises a tubular cover 32 and a shaft 34. Cover 32 has a central lumen 36 extending from a proximal end 38 to a distal end 40. Shaft 34 is slidably received within central lumen 36 and extends proximally of cover 32." (emphasis added)

The Fogarty Patent, col. 9, ll. 19-24. Thus, Fogarty, referring to Figure 2, provides that the cover 32 extends from the end 38 to end 40, which means that the cover extends over the entire length of the shaft. This is also readily apparent from Figure 2. Furthermore, as can be easily inferred from Figure 2, the end 38 of cover 32 is connected to element 50 and, therefore, the cover is integral with the delivery system.

In sharp contrast, the flexible sleeve of the present invention does not extend over the entire length of the outer shaft and is not integral with the delivery system. The flexible sleeve is primarily used to house the prosthesis.

Cover 32 of Fogarty can hardly be equated with the sleeve of the instant invention. As we noted earlier, the sleeve is flexible whereas there is nothing in Fogarty to suggest that the cover 32 is flexible and it cannot be presumed so. The present invention is directed to delivery systems for prosthesis, such as self-expanding stents, that require a large compressive force to reduce them to a compressed state for delivery into a body lumen. In the present invention the prosthesis is restrained in the compressive state by a flexible sleeve. In contrast, Fogarty, which, by the way, is not concerned with the delivery of self-expanding stents, holds the prosthesis between flexible runners 42. Thus, the function performed by the sleeve of the present invention appears to be performed, if at all, by the runners in Fogarty. Therefore, if

flexibility is to be attributed to an element of Fogarty, it would be to the runners, which arguably perform a function similar to that of the sleeve of the present invention, but certainly not to the cover 32. Clearly, then, Fogarty does not in the least suggest or imply that the cover 32 is flexible, an express limitation of amended claim 2, 15 and 39.

The foregoing points up another significant difference between Fogarty and the present invention. The prosthesis in the present invention's delivery system is sandwiched between the sleeve and the prongs of the securing member. On the other hand, the prosthesis in the Fogarty is secured by the runners, which are sandwiched between the cover 32 and the prosthesis. Thus, in Fogarty the runners are outside the prosthesis whereas the prongs of the present invention are on the inside of the prosthesis. See Figures 10B and 10C.

In sum, Fogarty discloses a device that has a substantially different structure than the device of the present invention. The runners 42 and the outer cover 32 both lie on the outside of the prosthesis in a compressed state. In contrast, the present invention claims a delivery system where the sleeve encloses the compressed prosthesis on the outside but the securing member holds the prosthesis from the inside.

Finally, each of the claims 39-40 includes the following express limitation contained in claim 39: "wherein said intraluminal prosthesis is a self-expandable stent." At the very least, Fogarty does not disclose such a prosthesis. In fact, as a person of ordinary skill in the art will recognize, the runners and the cover of Fogarty cannot be used to house a self-expanding stent in a compressed state. Because Fogarty does not disclose "a self-expandable stent" as the prosthesis, Fogarty fails to disclose the preceding limitation and, therefore, does not anticipate any of the claims 39-40.¹

Applicant respectfully submits that, for the foregoing reasons, claims 2, 6-12, 15-17, and 39-40 are allowable over Fogarty. A notice of allowance is, therefore, respectfully requested.

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¹ None of the foregoing should be construed as an admission that the cited reference discloses any of the other limitations of claims 39-40.